

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 08 MAY 2006
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
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Date of mailing (day/month/year) **04 MAY 2006**

Applicant's or agent's file reference 00786-813WO1	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/US04/25146	International filing date (day/month/year) 02 August 2004 (02.08.2004)	Priority date (day/month/year) 01 August 2003 (01.08.2003)
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International Patent Classification (IPC) or both national classification and IPC

IPC: **G01V 03/00; G06Q 10/00 (2006.01) C12Q 01/68**
 USPC: **705/2; 702/20; 435/6**

Applicant
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

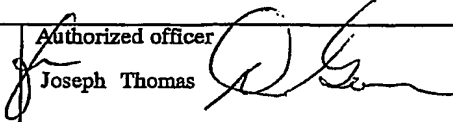
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 20 March 2006 (20.03.2006)	Authorized officer Joseph Thomas  Telephone No. 571-272-3600
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/25146

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/25146

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-138</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-138</u>	NO
Industrial applicability (IA)	Claims <u>1-138</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-138 lack an inventive step under PCT Article 33(3) as being obvious over Scott (USPN 2002/0095585 A1) in view of Cohen et al (US 6,476,208).

Scott discloses a data structure for storing genetic information/profiles for individuals to facilitate comparative studies and genetic mapping for populations with certain illnesses and or diseases. (paragraphs 13-16). Genetic information/profiles from a plurality of participants is pooled in a distributed database to facilitate queries (par. 46-48)

Scott discloses that the personal genomic profile information stored by the system may include genotype information, gene expression information, proteomics information, phenotype information, and medical information of a participant. Genomic information can include, for example, gene expression profiling; DNA sequence, structure, expression, or function information; RNA sequence, structure, expression, or function information; protein sequence, structure, expression, or function information; genotypic and phenotypic variation information; pharmacogenomic information; pharmacogenetic information; genomic pathology information; molecular pathology; molecular profiling; pathway information; and any related biochemical information or molecular information of a participant. (par. 75-76)

Scott does not expressly disclose the system and method as applied to storing data regarding data on the brain, brain injuries and neurological development. Cohen discloses a system and method for identifying and storing information regarding genetic markers and alleles associated with the brain. (col. 9, lines 22-47) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of teachings of Cohen to provide genetic information on illnesses associated with the brain, brain injuries and neurological development. One would have been motivated to include this feature to facilitate detection certain psychiatric illnesses or susceptibility to certain psychiatric diseases, thereby reducing the medical risks, which may result if these diseases go untreated. (Cohen: col. 115, lines 6-26)

Claims 1-138 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.